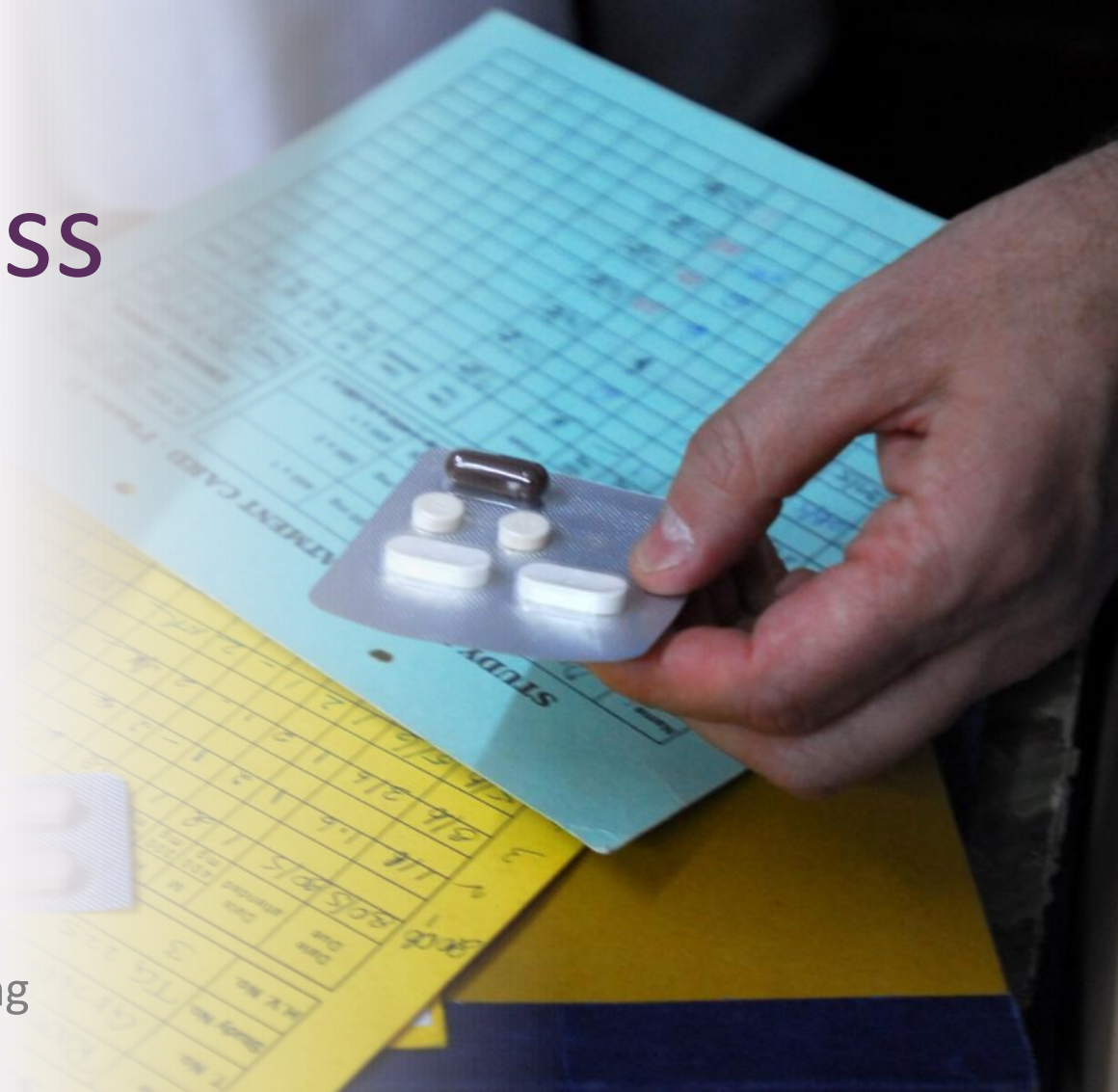


# Market Access Highlights

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Stakeholders Association Meeting

November 16, 2012



**TB ALLIANCE**

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

# Today's Discussion

1. Planning for REMox Introduction
2. Drug Susceptibility Testing
3. Impact of Shorter Treatments on Patients
4. Pediatrics

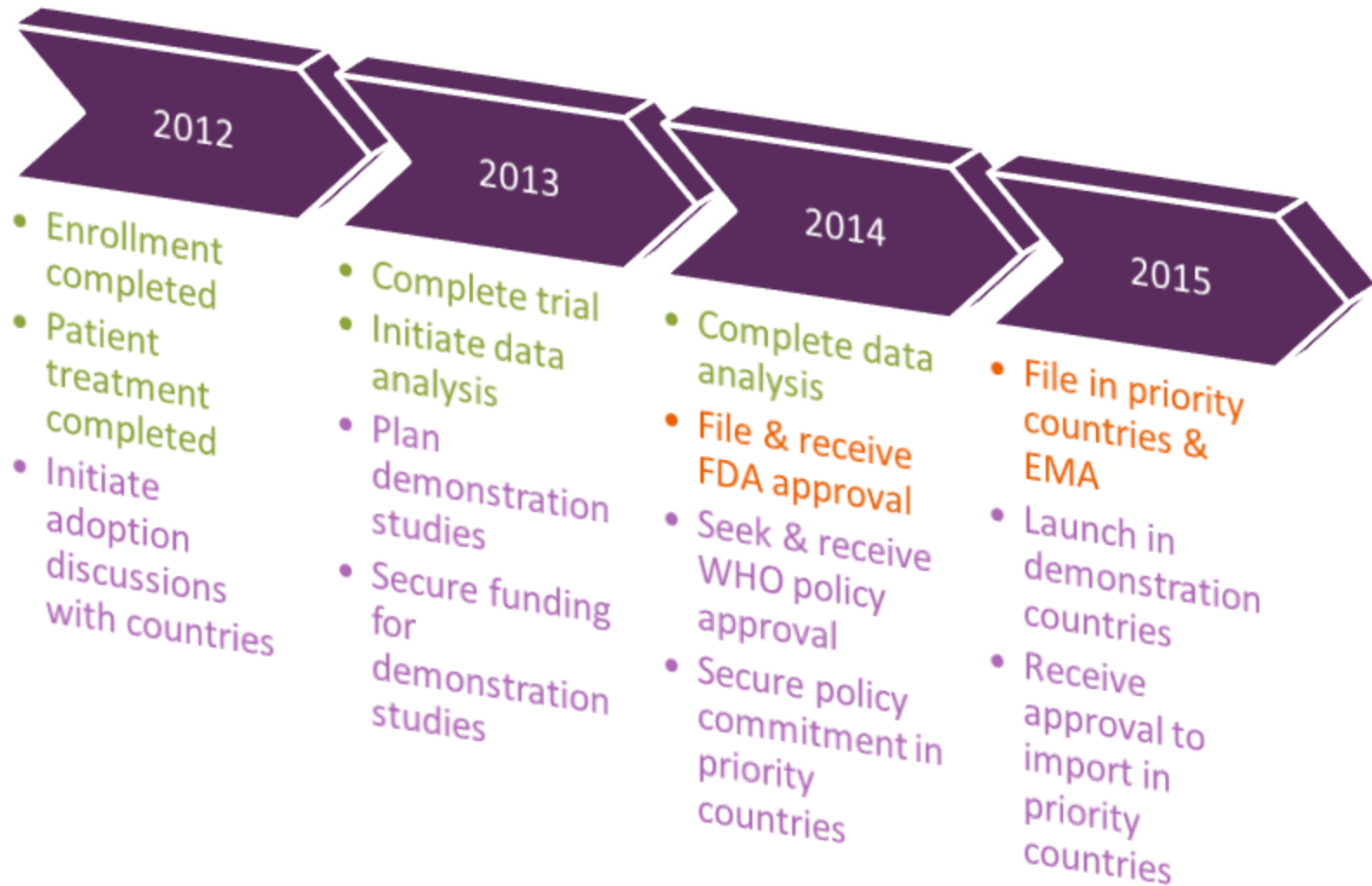


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# Timeline for REMox TB

Clinical, Regulatory and Market Access activities in brief



# Moxifloxacin Plan

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- Achieve product adoption as soon as possible in at least a few (2-3) high burden countries to demonstrate success
  - e.g. prioritize early adoption success in a few key countries to increase uptake in others

# Recommended Countries for Prioritization

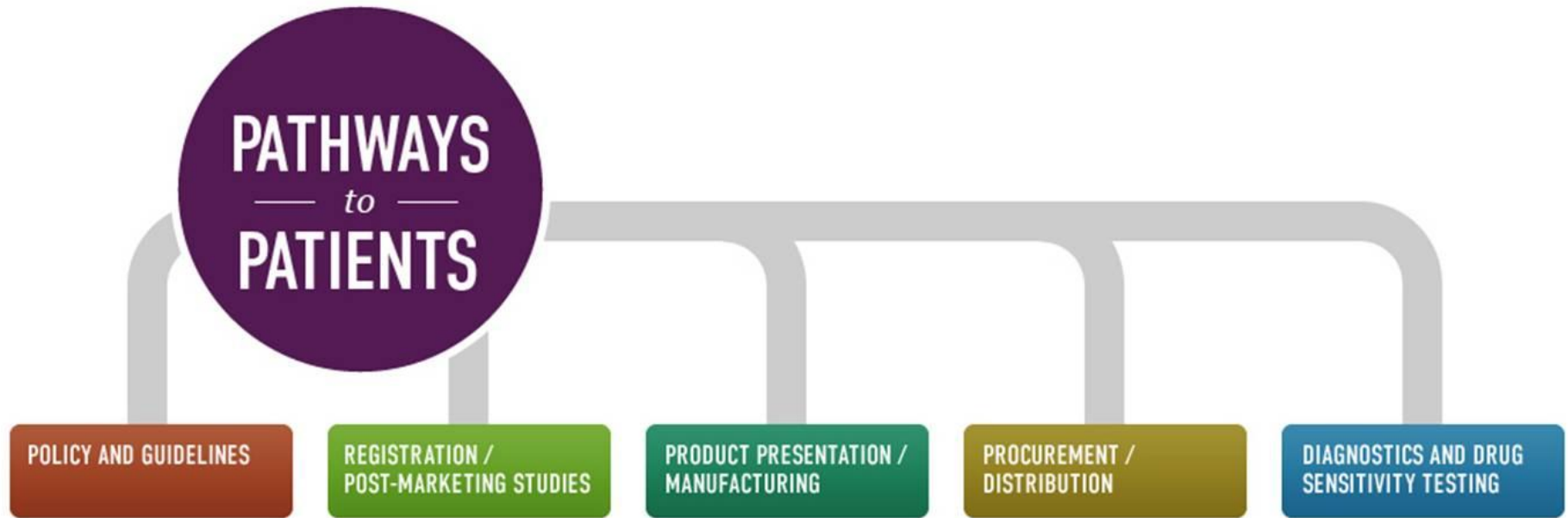
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To be confirmed with countries - some will drop out

- Public Sector
  - High Priority
    - Europe, US
    - Kenya, Tanzania
    - Bangladesh, Cambodia
    - Brazil, South Africa
    - DRC, Ethiopia
  - Priority
    - Philippines, Vietnam, Thailand, Myanmar
    - India, China, Indonesia
- Private Sector: Some countries expected to be early adopters
  - India, Indonesia, Pakistan, Nigeria, China, Philippines
- Could also prioritize particular *populations*
  - Refugees, migrants? Rural populations far from treatment centers?
  - PLWHA?

# Steps to new product introduction

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**Advocacy for regimen change is the foundation**

# Cost of REMox Regimen

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All 4 drugs in regimen off patent by time of launch

- Current cost of REMox: ~ \$100, same as HRZE about 20 years ago
- Cost expected to decline as more quality suppliers enter the market
- Long term target price for regimen: \$35

# Next Steps in launch planning

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Input and advice welcome from SHA

- Identify countries that want to be early adopters
- Plan for launch and demonstration studies in 2-4 countries, including budgets
- Identify additional suppliers and finalize patient kits for public and private sectors
- Assess cost effectiveness
- Secure funds for launch and demonstration studies

**Advocate for informed discussions on regimen change**



## 2) Diagnostics & Drug Susceptibility Testing

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Resistance as a factor in usage & adoption decision-making

- Population-level: Surveillance among new patients
  - Understand “background resistance” levels to FQs & first line drugs
  - So far, only data on FQs from Belarus
  - Gates, TB Alliance, USAID committing funds to support WHO to work with countries on additional testing
- Individual level: Drug Sensitivity Testing
  - Roll out of Hain test following initial WHO approval
  - Other tests in development, e.g. cartridges for GeneXpert
- Testing/Treatment Algorithms under discussion
  - Presumptive treatment, R as indicator, DST for all drugs, etc.

### 3) Impact of Shorter Regimens on Patients

Study conducted in Tanzania and Bangladesh

	Tanzania	Bangladesh
Cost/patient of final two months of treatment	\$ 74	\$ 56
Cost in final two months as % of the average national income during same period	77%	89%

- Patient costs are almost twice as high in the intensive phase, but still significant in the last 2 months
- Particularly high costs from lost work and food supplements

**Shortening treatment by just 2 months has significant impact**

# 4) Addressing Gaps in Pediatrics

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How we can get more children treated – and treated appropriately

- Product availability
  - HRZ, RH, E not available in correct doses or as dispersibles
  - Too long a lag time from adult to pediatric formulation availability
  - *Manufacturers need to be convinced of market viability*
- Understand Market
  - Size & location of public & private market (existing & potential)
  - Current treatment policies and practices
- Increase attention on pediatrics
  - Increase funding at global & country level
  - Encourage countries to prioritize pediatrics & allocate resources

# Addressing Gaps in Pediatrics (cont.)

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How we can get more children treated – and treated appropriately

- Clinical studies
  - Obtain clinical evidence as needed
  - Build consensus around study design
- Regulatory pathways
  - Provide greater clarity to manufacturers, policy makers, clinical researchers
  - Identify and agree ways to shorten pathway to registration, safely
- Disseminate learning
  - Create Pediatric Center of Excellence
  - Apply learning to existing and new drugs to speed market entry

**Shorten development time so pediatric formulations are available closer to the time adult formulations come on the market**